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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| EXAMINER | |
|---|---|
| CLARK, AMY LYNN | |
| **ART UNIT** | **PAPER NUMBER** |
| 1655 | |

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/524,015 | ENOKI ET AL. | |
| | Examiner | Art Unit | |
| | Amy L. Clark | 1655 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *25 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *11-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 February 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/13/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

The finality of the final rejection dated 14 July 2006 and mailed out on 25 July 2006 has been vacated.

Acknowledgment is made of the receipt and entry of the amendment filed after final on 25 October 2006 with the amendment of Claims 11, 13, 14, 16 and 17.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 11-17 are under examination.**

### *Information Disclosure Statement*

The information disclosure statement filed 13 November 2006 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the reference provided by Applicant has not been translated into English nor has Applicant provided an English translation of the abstract. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

***Specification***

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: "An (agent, food, beverage or feed) comprising (specific type of extract of specific plant) for treating (specific disease)".

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of Claims 11, 13, 14, 16 and 17 are rendered uncertain by the phrase "an extract of a plant selected from the group consisting of *Angelica keiskei* koidz. and *Cryptotaenia japonica* Hassk as an effective ingredient," because it is unclear if Applicant is claiming an extract, wherein the extract is *Angelica keiskei* koidz. or an extract, wherein the extract is *Cryptotaenia japonica* Hassk or if Applicant is claiming an extract obtained from *Angelica keiskei* koidz. or *Cryptotaenia japonica* Hassk. Furthermore, it is unclear as to what type of extract of *Angelica keiskei* koidz. or *Cryptotaenia japonica* Hassk Applicant is referring to. For example, Applicant could be claiming an aqueous/organic extract or Applicant could be claiming a specific compound extracted from *Angelica keiskei* koidz. or *Cryptotaenia japonica* Hassk. The lack of

clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

***Response to Arguments***

***Claim Rejections - 35 USC § 112***

Newly amended Claims 11-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement is considered in view of the *Wands* factors (MPEP 2164.O1(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art predictability of the art and the amount of experimentation necessary. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

*Nature of the Invention*: The claims are drawn to a therapeutic agent or prophylactic agent for treating or preventing a disease characterized by an abnormal response to insulin or abnormal insulin levels, wherein the agent comprises an extract of a plant selected from the group consisting of *Angelica keiskei* koidz. and *Cryptotaenia japonica* Hassk as an effective ingredient, a therapeutic agent or prophylactic agent for treating or preventing a disease characterized by an abnormal response to insulin or

abnormal insulin levels, wherein the agent comprises an extract of a plant selected from the group consisting of *Angelica keiskei* koidz. and *Cryptotaenia japonica* Hassk as an effective ingredient, wherein the disease is selected from the group consisting of diabetes, obesity, arterial sclerosis, cocaine withdrawl symptoms, static cardiac incompetence, cardiovascular seizure, cerebral angiospasm, chromaffinomosa, ganlioneuroblastoma, Huntington's disease, Alzheimer's disease, hyperlipemia and hyperinsulinemia, a food, beverage or feed for treating or preventing a disease characterized by an abnormal response to insulin or abnormal insulin levels, wherein the food, beverage or feed comprises an extract of a plant selected from the group consisting of *Angelica keiskei* koidz. and *Cryptotaenia japonica* Hassk as an effective ingredient, a food, beverage or feed for treating or preventing a disease characterized by an abnormal response to insulin or abnormal insulin levels, wherein the food, beverage or feed comprises an extract of a plant selected from the group consisting of *Angelica keiskei* koidz. and *Cryptotaenia japonica* Hassk as an effective ingredient, wherein the disease is selected from the group consisting of diabetes, obesity, arterial sclerosis, cocaine withdrawl symptoms, static cardiac incompetence, cardiovascular seizure, cerebral angiospasm, chromaffinomosa, ganlioneuroblastoma, Huntington's disease, Alzheimer's disease, hyperlipemia and hyperinsulinemia, an agent for the enhancement of glucose uptake into a cell, comprising an extract of a plant selected from the group consisting of *Angelica keiskei* koidz. and *Cryptotaenia japonica* Hassk as an effective ingredient, an agent for the enhancement of glucose uptake into a cell, comprising an extract of a plant selected from the group consisting of *Angelica keiskei*

koidz. and *Cryptotaenia japonica* Hassk as an effective ingredient, and an agent for the induction of adipocyte, differentiation comprising an extract of a plant selected from the group consisting of *Angelica keiskei* koidz. and *Cryptotaenia japonica* Hassk as an effective ingredient.

*Breadth of the Claims*: The claims are broad in that a therapeutically effective amount of an agent, any food, beverage or feed comprising any amount of any extract of *Angelica keiskei* koidz. or *Cryptotaenia japonica* Hassk may be administered to treat or prevent any disease characterized by an abnormal response to insulin or abnormal insulin levels, or a disease characterized by an abnormal response to insulin or abnormal insulin levels, wherein the disease is selected from the group consisting of diabetes, obesity, arterial sclerosis, cocaine withdrawl symptoms, static cardiac incompetence, cardiovascular seizure, cerebral angiospasm, chromaffinomosa, ganlioneuroblastoma, Huntington's disease, Alzheimer's disease, hyperlipemia and hyperinsulinemia, and that an agent comprising any amount of any extract of *Angelica keiskei* koidz. or *Cryptotaenia japonica* Hassk enhancement of glucose uptake into a cell, and induction of adipocyte differentiation comprising any extract of a plant selected from the group consisting of *Angelica keiskei* koidz. and *Cryptotaenia japonica* Hassk as an effective ingredient in a patient. The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims.

*Guidance of the Specification and Existence of Working Examples*: The specification describes an extract of *Angelica keiskei* koidz root and leaf of *Angelica keiskei* koidz and an *in vitro* method of induction of adiposyte differentiation by different

extracts from *Angelica keiskei* koidz, *in vitro* method of enhancing action for glucose uptake of extract from *Angelica keiskei* koidz (See Examples1-7, 14-18), a method of inhibition of enhancing action for glucose extract from root of *Angelica keiskei* by cytochalasin B, a method of inhibition of enhancing action of glucose and insulin uptake by ethanol extract from *Angelica keiskei*, a method of enhancing glucose uptake by insulin stimulation into adipocyte induced to be different by extract fraction from root portions or yellow sap of *Angelica keiskei* (See Examples 19-25), and a method of measuring the effect of ethanol extraction of root or yellow sap of *Angelica keiskei* using type II diabetes model mouse on blood glucose (See Example 26).

The specification envisions that a therapeutically effective amount of an agent, or any type of food, beverage or feed comprising any amount of any extract of *Angelica keiskei* koidz. or any extract of *Cryptotaenia japonica* Hassk will have utility in humans in treating or preventing any disease characterized by an abnormal response to insulin or abnormal insulin levels, that a therapeutically effective amount of an agent, or any type of food, beverage or feed comprising any amount of any extract of *Angelica keiskei* koidz. or *Cryptotaenia japonica* Hassk will have utility in humans in treating or preventing any disease characterized by an abnormal response to insulin or abnormal insulin levels, wherein the disease is selected from the group consisting of diabetes, obesity, arterial sclerosis, cocaine withdrawl symptoms, static cardiac incompetence, cardiovascular seizure, cerebral angiospasm, chromaffinomosa, ganlioneuroblastoma, Huntington's disease, Alzheimer's disease, hyperlipemia and hyperinsulinemia, that an agent comprising any amount of any extract of *Angelica keiskei* koidz. or any extract of

*Cryptotaenia japonica* Hassk will have utility in humans in will have utility in humans in enhancing glucose uptake into a cell, and comprising any amount of any extract of *Angelica keiskei* koidz. or any extract of *Cryptotaenia japonica* Hassk will have utility in humans in induction of adipocyte differentiation.

However, no working examples are provided with regard to any therapeutic or prophylactic agent, or any type of food, beverage or feed comprising any amount of any extract of *Angelica keiskei* koidz. or any extract of *Cryptotaenia japonica* Hassk for treating or preventing any disease characterized by an abnormal response to insulin or abnormal insulin levels, or a disease characterized by an abnormal response to insulin or abnormal insulin levels, wherein the disease is selected from the group consisting of diabetes, obesity, arterial sclerosis, cocaine withdrawl symptoms, static cardiac incompetence, cardiovascular seizure, cerebral angiospasm, chromaffinomosa, ganlioneuroblastoma, Huntington's disease, Alzheimer's disease, hyperlipemia and hyperinsulinemia, and will have utility in humans in enhancing glucose uptake into a cell, and induction of adipocyte differentiation. Furthermore, no working examples are provided that demonstrate the efficacy of any therapeutic or prophylactic agent, or any type of food, beverage or feed comprising any amount of any extract of *Angelica keiskei* koidz. or any extract of *Cryptotaenia japonica* Hassk for treating or preventing any disease characterized by an abnormal response to insulin or abnormal insulin levels, or a disease characterized by an abnormal response to insulin or abnormal insulin levels, wherein the disease is selected from the group consisting of diabetes, obesity, arterial sclerosis, cocaine withdrawl symptoms, static cardiac incompetence, cardiovascular

seizure, cerebral angiospasm, chromaffinomosa, ganlioneuroblastoma, Huntington's disease, Alzheimer's disease, hyperlipemia and hyperinsulinemia, and will have utility in humans in enhancing glucose uptake into a cell, and induction of adipocyte differentiation.

*Predictability and State of the Art*: The state of the art at the time the invention was made was unpredictable and underdeveloped. For example, Shimura (Reference N, Japanese Patent Number 10-295325 A, Translation Provided Herein) teaches a health food obtained by extracting *Angelica keiskei* koidz. for treating various kinds of illnesses, such as blood-flow failure, cerebral apoplexy, hypertension, hangover, and diabetes mellitus, however, no working examples are provided.

Thus, while the claim-designated method may be useful for providing such an effect, Applicant does not disclose an extract of a plant selected from the group consisting of *Angelica keiskei* koidz. and *Cryptotaenia japonica* Hassk as an effective ingredient in treating or preventing all diseases characterized by an abnormal response to insulin or abnormal insulin levels, such as diabetes, arterial sclerosis, cocaine withdrawal symptoms, static cardiac incompetence, cardiovascular seizure, cerebral angiospasm, chromaffinomosa, ganglioneuroblastoma, Huntington's disease, hyperlipemia, and hyperinsulinemia. The Office further notes that while the specification discloses that the claim-designated methods and claim designated compositions will have utility in humans in treating such as obesity, diabetes, arterial sclerosis, cocaine withdrawal symptoms, static cardiac incompetence, cardiovascular seizure, cerebral angiospasm, chromaffinomosa, ganglioneuroblastoma, Huntington's disease,

hyperlipemia, and hyperinsulinemia, nowhere in the specification or in the limitations does Applicant direct the claimed subject matter to the administration of an agent or any type of food, beverage or feed comprising any type of extract of any plant part, wherein the plant is selected from the group consisting of *Angelica keiskei* koidz. and *Cryptotaenia japonica* Hassk as an effective ingredient to any subject.

It should be noted that at the time of filing of the present application, the art of medicine did not recognize the administration of an agent or any type of food, beverage or feed comprising any type of extract of any plant part, wherein the plant is selected from the group consisting of *Angelica keiskei* koidz. and *Cryptotaenia japonica* Hassk as an effective ingredient, wherein said an agent or any type of food, beverage or feed comprising any type of extract of any plant part, wherein the plant is selected from the group consisting of *Angelica keiskei* koidz. and *Cryptotaenia japonica* Hassk as an effective ingredient for treating or preventing all diseases characterized by an abnormal response to insulin or abnormal insulin levels, such as obesity, diabetes, arterial sclerosis, cocaine withdrawal symptoms, static cardiac incompetence, cardiovascular seizure, cerebral angiospasm, chromaffinomosa, ganglioneuroblastoma, Huntington's disease, hyperlipemia, and hyperinsulinemia in humans.

*Amount of Experimentation Necessary*: The quantity of experimentation necessary to carry out the claimed invention is high, as the skilled artisan could not rely on the prior art or instant specification to teach how to make and use any an agent or any type of food, beverage or feed comprising any type of extract of any plant part, wherein the plant is selected from the group consisting of *Angelica keiskei* koidz. and

*Cryptotaenia japonica* Hassk as an effective ingredient in treating or preventing all diseases characterized by an abnormal response to insulin or abnormal insulin levels, such as obesity, diabetes, arterial sclerosis, cocaine withdrawal symptoms, static cardiac incompetence, cardiovascular seizure, cerebral angiospasm, chromaffinomosa, ganglioneuroblastoma, Huntington's disease, hyperlipemia, and hyperinsulinemia in humans. In order to carry out the claimed invention, one of ordinary skill in the art would have to identify an agent or any type of food, beverage or feed comprising any type of extract of any plant part, wherein the plant is selected from the group consisting of *Angelica keiskei* koidz. and *Cryptotaenia japonica* Hassk that can be administered in a therapeutically effective dose with an acceptable level of side-effects.

In view of the breadth of the claims and the lack of guidance provided by the specification as well as the unpredictability of the art, the skilled artisan would have required an undue amount of experimentation to make and/or use the claimed invention. Therefore, Claims 11-17 are not considered to be fully enabled by the instant specification.

This rejection is maintained for reasons of record set forth in the paper mailed on 25 July 2006 and repeated below, slightly altered to take into consideration Applicant's amendment filed on 15 October 2006.

Applicant's arguments have been thoroughly considered, but the rejection remains the same for the reasons set forth in the previous Office action and for the reasons set forth below.

Applicant argues that in order to establish a prima facie case of non-enablement,

the Examiner must explain why the specification is not enabled based on sound scientific reasoning or acceptable evidence, which is inconsistent with statements in the specification asserting enablement. (In re Marzocchi, 169 USPQ 367 (CCPA 1971). Applicant further argues that the Examiner has not established such reasoning or evidence, in that the Examiner asserts that the specification is not enabling because no working examples are provided that demonstrate the efficacy of the claimed plant extracts in treating insulin-related diseases (page 5 of the previous Office Action) and that Example 26 on page 55, in the specification as filed, demonstrates the efficacy of the inventive agents in treating diabetes, and insulin-related disease. Applicant further argues that Example 26 shows that when 5 mL/kg of *Angelica keiskei* koidz extract is administered for seven days to type II diabetes model mice, the mice' blood glucose levels are remarkably lowered, thus, as Applicants assert in the specification, the inventive extracts are useful to ameliorate the effects of insulin-related diseases, such as diabetes (page 55, lines 9-10). Applicant further argues that Applicant is not obligated to provide an exhaustive number of working examples to show enablement. Enablement can be provided through broad terminology or illustrative examples. In re Marzocchi, id at 369 and that the Examiner, also, is incorrect in asserting that "nowhere in the specification does Applicant direct the claimed subject matter to the administration of compositions comprising an extract of a plant...as an effective ingredient in any subject." (Office Action, page 6) and that in contrast to the Examiner's assertion, the specification does teach how to administer the inventive extracts, as well as how to make them. Applicant further argues that Applicant has provided numerous

examples of how to make the instant extracts (See, e.g. Examples 1, 2, 6, 8, 11, 14, 22, 24, and 25) and that the specification teaches methods for the administration, dosage level, dosage form and formulation of these inventive extracts, and also provides guidance by teaching preferred methods (See, e.g. pages 13 at lines17 through to page 16 at line 22 in the specification as filed). Applicant further argues that specifically, with respect to formulations, the specification teaches that the dose of the inventive agents is about 0.1 g to 1 g/kg weight for humans per day (page 16) and preferably 0.01 mg to 2000 mg, per day per 1 kg of the body weight of a subject organism (page 23 at lines 18-21) and that page 14 in the instant specification provides guidance on particular pharmaceutical carriers and adjuvants used in formulations and that the specification, also, teaches that the optimal dosages to be administered will vary and may be determined by those skilled in the art depending on a variety of factors which are listed thereafter (page 14 at lines 7-20), we contend that the specification is sufficiently enabled such that a skilled artisan recognizes how to make the inventive extracts and how to use them to treat insulin-related disorders. Applicant further argues that the Examiner does not provide any objective evidence that would cause a skilled artisan to doubt that the inventive plant extracts may be used to treat insulin-related disorders and that although the Examiner cites Japanese Patent No. 05-255100 to Shimura ("Shimura") to support the Examiner's contention that the art is unpredictable, this reference only acts to support Applicants' statements and that the Shimura reference discloses that *Angelica pubescens* extract may be used to treat obesity (See, abstract on page 2 of the Shimura reference) and that thus although the Shimura reference

allegedly fails to describe an efficacious dose of *Angelica pubescens* or provide any *in vivo* examples, this reference does not contradict Applicants' assertion that the present agents may be used to treat insulin-related disorders and, therefore, Applicants contend that by following the guidance provided in the instant specification, the skilled artisan understands how to make the inventive plant extracts, as well as how to use them to treat subjects having insulin related disorders or as a prophylactic against such disorders and that, thus, one of ordinary skill can practice the claimed invention without undue experimentation.

However, this is not found persuasive because the claims are broad in that a therapeutically effective amount of an agent, any food, beverage or feed comprising any amount of any extract of *Angelica keiskei* koidz. or *Cryptotaenia japonica* Hassk may be administered to treat or prevent any disease characterized by an abnormal response to insulin or abnormal insulin levels, or a disease characterized by an abnormal response to insulin or abnormal insulin levels, wherein the disease is selected from the group consisting of diabetes, obesity, arterial sclerosis, cocaine withdrawl symptoms, static cardiac incompetence, cardiovascular seizure, cerebral angiospasm, chromaffinomosa, ganlioneuroblastoma, Huntington's disease, Alzheimer's disease, hyperlipemia and hyperinsulinemia, and that an agent comprising any amount of any extract of *Angelica keiskei* koidz. or *Cryptotaenia japonica* Hassk enhancement of glucose uptake into a cell, and induction of adipocyte differentiation comprising any extract of a plant selected from the group consisting of *Angelica keiskei* koidz. and *Cryptotaenia japonica* Hassk as

an effective ingredient in a patient. The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims.

The specification envisions that a therapeutically effective amount of an agent, or any type of food, beverage or feed comprising any amount of any extract of *Angelica keiskei* koidz. or any extract of *Cryptotaenia japonica* Hassk will have utility in humans in treating or preventing any disease characterized by an abnormal response to insulin or abnormal insulin levels, that a therapeutically effective amount of an agent, or any type of food, beverage or feed comprising any amount of any extract of *Angelica keiskei* koidz. or *Cryptotaenia japonica* Hassk will have utility in humans in treating or preventing any disease characterized by an abnormal response to insulin or abnormal insulin levels, wherein the disease is selected from the group consisting of diabetes, obesity, arterial sclerosis, cocaine withdrawl symptoms, static cardiac incompetence, cardiovascular seizure, cerebral angiospasm, chromaffinomosa, ganlioneuroblastoma, Huntington's disease, Alzheimer's disease, hyperlipemia and hyperinsulinemia, that an agent comprising any amount of any extract of *Angelica keiskei* koidz. or any extract of *Cryptotaenia japonica* Hassk will have utility in humans in will have utility in humans in enhancing glucose uptake into a cell, and comprising any amount of any extract of *Angelica keiskei* koidz. or any extract of *Cryptotaenia japonica* Hassk will have utility in humans in induction of adipocyte differentiation. However, no working examples are provided with regard to any therapeutic or prophylactic agent, or any type of food, beverage or feed comprising any amount of any extract of *Angelica keiskei* koidz. or any extract of *Cryptotaenia japonica* Hassk for treating or preventing any disease

characterized by an abnormal response to insulin or abnormal insulin levels, or a disease characterized by an abnormal response to insulin or abnormal insulin levels, wherein the disease is selected from the group consisting of diabetes, obesity, arterial sclerosis, cocaine withdrawl symptoms, static cardiac incompetence, cardiovascular seizure, cerebral angiospasm, chromaffinomosa, ganlioneuroblastoma, Huntington's disease, Alzheimer's disease, hyperlipemia and hyperinsulinemia, and will have utility in humans in enhancing glucose uptake into a cell, and induction of adipocyte differentiation. Furthermore, no working examples are provided that demonstrate the efficacy of any therapeutic or prophylactic agent, or any type of food, beverage or feed comprising any amount of any extract of *Angelica keiskei* koidz. or any extract of *Cryptotaenia japonica* Hassk for treating or preventing any disease characterized by an abnormal response to insulin or abnormal insulin levels, or a disease characterized by an abnormal response to insulin or abnormal insulin levels, wherein the disease is selected from the group consisting of diabetes, obesity, arterial sclerosis, cocaine withdrawl symptoms, static cardiac incompetence, cardiovascular seizure, cerebral angiospasm, chromaffinomosa, ganlioneuroblastoma, Huntington's disease, Alzheimer's disease, hyperlipemia and hyperinsulinemia, and will have utility in humans in enhancing glucose uptake into a cell, and induction of adipocyte differentiation. Furthermore, the state of the art at the time the invention was made was unpredictable and underdeveloped. For example, Shimura (Reference N, Japanese Patent Number 10-295325 A, Translation Provided Herein) teaches a health food obtained by extracting *Angelica keiskei* koidz. for treating various kinds of illnesses, such as blood-flow failure,

cerebral apoplexy, hypertension, hangover, and diabetes mellitus, however, no working examples are provided.

In response to Applicant's argument that in order to establish a *prima facie* case of non-enablement, the Examiner must explain why the specification is not enabled based on sound scientific reasoning or acceptable evidence, which is inconsistent with statements in the specification asserting enablement. (In re Marzocchi, 169 USPQ 367 (CCPA 1971). Applicant further argues that the Examiner has not established such reasoning or evidence, in that the Examiner asserts that the specification is not enabling because no working examples are provided that demonstrate the efficacy of the claimed plant extracts in treating insulin-related diseases (page 5 of the previous Office Action) and that Example 26 on page 55, in the specification as filed, demonstrates the efficacy of the inventive agents in treating diabetes, and insulin-related disease, that Example 26 shows that when 5 mL/kg of *Angelica keiskei* koidz extract is administered for seven days to type II diabetes model mice, the mice' blood glucose levels are remarkably lowered, thus, as Applicants assert in the specification, the inventive extracts are useful to ameliorate the effects of insulin-related diseases, such as diabetes (page 55, lines 9-10)

In response to all of Applicant's arguments, please not the following. Applicant's specification makes many allegations as to what the effect of extracts of *Angelica keiskei* koidz. and *Cryptotaenia japonica* Hassk are in humans, however, **no evidence is provided to support these assertions**. The closest *in vivo* example that is provided by Applicant in the specification is found in Examples 19-25, in which a study was

conducted on a method of enhancing glucose uptake by insulin stimulation into adipocyte induced to be different by extract fraction from root portions or yellow sap of *Angelica keiskei*, and a method of measuring the effect of ethanol extraction of root or yellow sap of *Angelica keiskei* on blood glucose using type II diabetes model mouse (See Example 26). Please note that this does not prove that all types of *Angelica keiskei* extracts are capable of treating or preventing any disease characterized by an abnormal response to insulin or abnormal insulin levels, or a disease characterized by an abnormal response to insulin or abnormal insulin levels, wherein the disease is selected from the group consisting of diabetes, obesity, arterial sclerosis, cocaine withdrawl symptoms, static cardiac incompetence, cardiovascular seizure, cerebral angiospasm, chromaffinomosa, ganlioneuroblastoma, Huntington's disease, Alzheimer's disease, hyperlipemia and hyperinsulinemia, and will have utility in humans in enhancing glucose uptake into a cell, and induction of adipocyte differentiation, nor is there any in vivo evidence, either in the specification or in the art at the time of filing, that any or all extracts of any or all parts of *Cryptotaenia japonica* Hassk incorporated into any or all types of food, beverage or feed or in the form of an agent is capable of treating or preventing any disease characterized by an abnormal response to insulin or abnormal insulin levels, or a disease characterized by an abnormal response to insulin or abnormal insulin levels, wherein the disease is selected from the group consisting of diabetes, obesity, arterial sclerosis, cocaine withdrawl symptoms, static cardiac incompetence, cardiovascular seizure, cerebral angiospasm, chromaffinomosa, ganlioneuroblastoma, Huntington's disease, Alzheimer's disease, hyperlipemia and

hyperinsulinemia, and will have utility in humans in enhancing glucose uptake into a cell, and induction of adipocyte differentiation. Furthermore, irrespective of whether an extract fraction from root portions or yellow sap of *Angelica keiskei* enhanced glucose uptake by insulin stimulation , or an ethanol extraction of root or yellow sap of *Angelica keiskei* had an effect on on blood glucose using type II diabetes model mouse extracts, there is no indication that there is any influence on all diseases characterized by an abnormal response to insulin or abnormal insulin levels, or a disease characterized by an abnormal response to insulin or abnormal insulin levels, wherein the disease is selected from the group consisting of diabetes, obesity, arterial sclerosis, cocaine withdrawl symptoms, static cardiac incompetence, cardiovascular seizure, cerebral angiospasm, chromaffinomosa, ganlioneuroblastoma, Huntington's disease, Alzheimer's disease, hyperlipemia and hyperinsulinemi. Furthermore, **at the time the invention was made, the state of the art did not recognize that any type of extract from *Angelica keiskei or Cryptotaenia japonica* had these effects in humans.** Please also note the following. The M.P.E.P. states, "**It is common that doubt arises about enablement because information is missing about one or more essential parts or relationships between parts which one skilled in the art could not develop without undue experimentation**. In such a case, the examiner should specifically identify what information is missing and why the missing information is needed to provide enablement" [See M.P.E.P. 2164.06(a)]. Please note that the Examiner has, in fact, provided adequate and specific reasoning for the enablement

rejection and described all of the relevant Wands factors in both this Office Action and the previous Office Action.

***Response to Arguments***

***Claim Rejections - 35 USC § 102***

Applicant's arguments, see "Applicant Arguments/Remarks Made in an Amendment", filed 25 October 2006, with respect to the rejection of claims 11, 12, 14 and 15 under 35 U.S.C. 102(b) as being anticipated by Cho (O*), of claims 11, 12 and 17 under 35 U.S.C. 102(b) as being anticipated by Shimura (P*) and claims 13 and 16 under 35 U.S.C. 102(b) as being anticipated by Yang et al. (U*) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Shimura (N, Japanese Patent Number 10-295325 A, Translation Provided Herein) and in view of Kawashimi (Q, Japanese Patent Number 08-154595 A, Translation Provided Herein).

Claims 11-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Shimura (N, Japanese Patent Number 10-295325 A, Translation Provided Herein).

Shimura teaches a health improver that has a SOD operation obtained from *Angelica keiskei*, the various functions nature matter (SOD) is extracted and it carries out to the health food containing this, and a health drink, i.e., health food.

It is noted that the reference does not teach that the composition can be used in all of the manners instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process claims.

Therefore, the reference anticipates the claimed subject matter.

Claims 11-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Kawashimi (Q, Japanese Patent Number 08-154595 A, Translation Provided Herein). Kawashimi teaches an a health food product and the induction active substance obtained from them comprising an extract from *Cryptotaenia japonica*, which is mixed

with a bait or feed for aquatic animals or is mixed with or absorbed into a proper carrier, which reads on agent and food, beverage or feed.

It is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

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Therefore, the reference anticipates the claimed subject matter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571) 272-1310. The examiner can normally be reached on 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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December 2, 2006

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